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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/139,386	08/25/1998	JOSEPH ALBERT MONFORTE	24736-2060	5243

24961 7590 10/06/2003

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

37

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/139,386

Applicant(s)
Monforte et al.

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 30, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendment filed 5/1/2003 has been entered. Following the entry of the amendment, claims 1-21 are pending.

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/30/2003 has been entered.
2. Applicant's arguments with respect to claims 1-21 in the Office action mailed 12/04/2002 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-15 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hiatt et al. (5,763,594, issued 6/1998).

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Hiatt et al. disclose a nucleic acid primer having a 5' end and a 3' end comprising:

- (a) a first region containing the 5' end of the primer and an immobilization attachment site (See column 17, lines 51-67 to column 18, lines 1-6).
- (b) a second region containing the 3' end of the primer and a selectively chemically cleavable site (See column 4, lines 61-67 and column 10, lines 21-62) wherein the 3' end is capable of being extended by an enzyme to generate an extension segment (See column 4, lines 5-11 and column 4, lines 55-58).

The selectively chemically cleavable site comprises a modified base or a modified sugar or a chemically cleavable group incorporated into the phosphate backbone including 3'-phosphorothioate, 3' phosphoramidate (See column 4, lines 61-67).

The enzyme is a DNA polymerase or ligase (See column 19, lines 38-55).

The intervening space arm is six or more atoms in length (See column 17, lines 54-63).

The solid support is selected from the group consisting of glass, silicon and as listed in claim 14 (See column 4, lines 49-54).

The solid support comprises a functionality selected from the group consisting of avidin and streptavidin (See column 19, lines 7-11).

Immobilization attachment site is biotin (See column 19, lines 7-11) or a single stranded nucleic acid (See column 17, lines 51-67).

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The teachings of Hiatt et al. do not explicitly disclose that a second region contains a selectively chemically cleavable. However, the chemically cleavable is always selective, based upon the analysis above. Thus, the teachings of Hiatt et al. anticipate the limitations of claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiatt et al. (5,763,594, issued 6/1998) as applied to claims 1-15 and 18-20 above, and further in view of Koster (5,547,835, issued 8/20/1996).

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The teachings of Hiatt et al. are set forth in section 4 above. Hiatt et al. do not disclose using the single stranded nucleic acid complementary to an intermediary oligonucleotide bound to the solid support.

Koster discloses a new method to sequence DNA. The nucleic acid oligonucleotide primer is involved in the method. The primer carries a linking functionality, L, at 5' end which can include a spacer arm and interact with a suitable functionality, L', on a solid support (See column 11, lines 52-63). The linkage has the purpose to capture the nested Sanger DNA or RNA fragment (See column 11, lines 66-67 to column 12, lines 1-30). The nested Sanger DNA/RNA fragments are captured via Watson-crick base pairing to a solid support-bound oligonucleotide complementary to the nucleic acid primer (See column 12, lines 51-56).

One of the ordinary skill in the art would have been motivated to modify the immobilization of the oligonucleotide of Hiatt et al. by applying the hybridization of the oligonucleotide on the solid support via nucleic acid linker as taught by Koster. Koster disclose that the solid support bound base sequence renders the base sequence less susceptible to enzymatic degradation and hence increases overall stability of the solid support-bound capture base sequence (See column 12, lines 57-65). It would have been prima facie obvious to have the single stranded nucleic acid which is complementary to an intermediary oligonucleotide bound to the solid support.

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7. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiatt et al. (5,763,594, issued 6/1998) as applied to claims 1-15 and 18-20 above, and further in view of Edwards et al. (5,306,619, issued 4/26/1994).

The teachings of Hiatt et al. are set forth in section 4 above. Hiatt et al. do not disclose that the solid support comprises an antibody comprising anti-digoxigenin.

Edwards et al. disclose a DNA:protein binding assay in which the target oligonucleotide is attached to a solid support by using an anti-digoxigenin which is attached on the solid support (See column 4, lines 51-56).

One of ordinary skill in the art would have been motivated to modify the solid support of Hiatt by using an anti-digoxigenin to attach the oligonucleotide to a solid support. Edward et al. states that the method is for identification of molecules that specifically bind to defined nucleic acid sequence (See column 1, lines 10-12 and column 2, lines 49-55). It would have been prima facie obvious to apply anti-digoxigenin to solid support to immobilize oligonucleotide.

Summary

8. No claims are allowable.

9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

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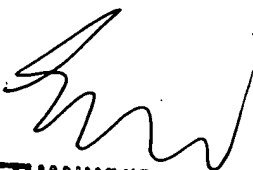
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

^{J.T.}
September 29, 2003


ETHAN WHISENANT
PRIMARY EXAMINER